

Biologics Effectiveness and Safety (BEST) Initiative: First Year

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Expansion of CBER Sentinel Program

INTRODUCTION

CBER Sentinel Vision is...

...to create and utilize an effective national post-market surveillance system for CBER-regulated products to provide data for evidence-based regulatory decisions to ensure the safe and effective use of biologic products.

CBER Regulated Products Biologics

- Vaccines (preventative and therapeutic) 
- Blood (components and derived) 
- Human Tissues and Cellular Products 
- Gene Therapies 
- Allergenic 
- Xenotransplantation Products 
- Devices Related to Biologics 

Uniqueness of Biologics

Safety Surveillance

- Newly approved products needing near-real time electronic health information
- Continuous and active surveillance during pandemics and epidemic emergence

Health Information

- Significantly different billing, coding, and reimbursement practices from drugs
- Need data from multiple sources: blood and tissue banks, registries, pharmacies, various point of care in different care settings

Population Characteristics


- Large sized data representing: healthy population and high risk populations like pregnant women, elderly, children, immunocompromised
- Long- follow up period

Priorities and Objectives in 2017

- To increase capacity to conduct more simple and complex queries
- To decrease the overall cost of running multiple studies
- To reduce the data lag giving us access to current data
- To access Electronic Health Record (EHR) data source which have clinical rich and granular data

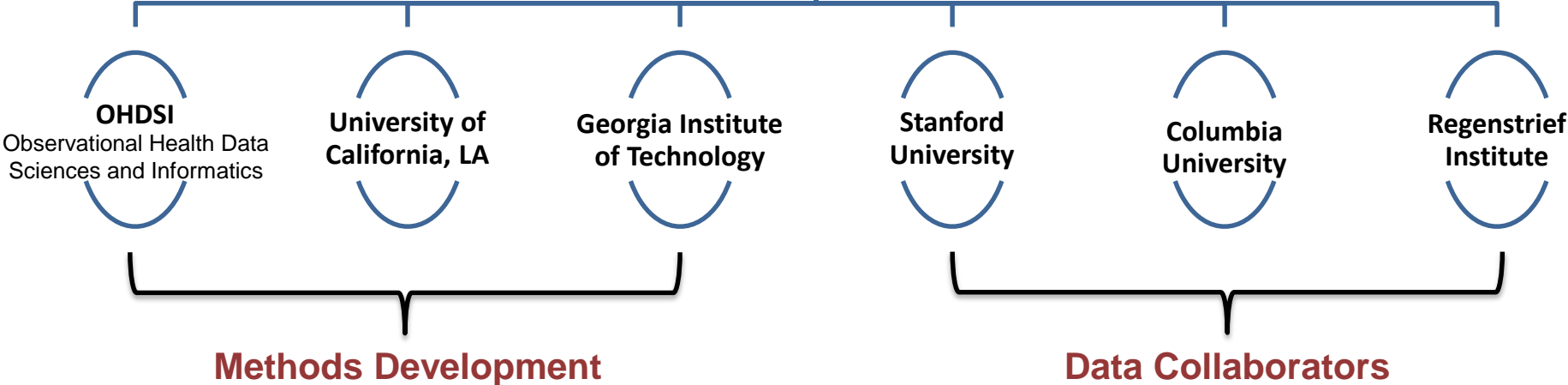


BEST
BIOLOGICS
EFFECTIVENESS &
SAFETY

- 
- Access diverse sources of electronic health care data
 - Expand network of multidisciplinary collaborators
 - Implement advanced and efficient scientific methodology for regulatory purposes
 - Construct a cost-effective and sustainable post-market surveillance program

BEST Collaborators

IQVIA*
Coordinating Center



*Also provides claims and hospital billing data

Objectives for Pilot Program

CONTRACT 1: Data, Tools and Infrastructure for Surveillance of Biologics

To develop additional surveillance capabilities specifically required for biologics:

- Access to EHR data sources

CONTRACT 2: Development of New and Innovative Methods for Automated Reporting

To utilize innovative methods such as natural language processing, machine learning, and artificial intelligence to mine unstructured data in EHR data sources

BEST Initiative: Data, Tools and Infrastructure for
Surveillance of Biologics

ACCOMPLISHMENTS: FIRST YEAR

Enhanced Infrastructure

Major expansion and enhancement of biologics surveillance system

- Addition of EHR data sources
- Shorter data lag: data refreshed at least quarterly
 - Less than 4 months

Data Sources

Claims/ Administration Billing Data

~100 million Patients

Data Sources:

IQVIA LRxDx
IQVIA Hospital Billing

Electronic Health Records Data

~20 million Patients

Data Sources:

Stanford University
Columbia University
Regenstrief Institute

Enhanced Infrastructure

Major expansion and enhancement of biologics surveillance system

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- Flexible and expandable common data model (CDM)

Enhanced Infrastructure

Major expansion and enhancement of biologics surveillance system

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- Flexible and expandable common data model (CDM)
- Access to flexible analytic capabilities

Flexibility with *ad hoc* Programming

- Programming for any questions of interest
- Iterations of programs after assessing feasibility

A decorative vertical pattern on the left side of the slide, consisting of repeating light blue and grey geometric shapes, including hexagons and vertical bars, resembling a molecular or cellular structure.

BEST Initiative: Data, Tools and Infrastructure for
Surveillance of Biologics

CHALLENGES

- Access to EHR
- Flexible CDM
- Direct communication with data partners



Strengths

- Data Quality
- Lack of Personnel
- Timeliness
- Quality of Deliverables



Weaknesses

- Expanding infrastructure needed for surveillance of biologics



Opportunities

- Unstable infrastructure
- Lose scientific and regulatory credibility



Threats

A decorative vertical pattern on the left side of the slide, featuring stylized molecular structures and chemical symbols in light blue and grey.

BEST Initiative: Data, Tools and Infrastructure for
Surveillance of Biologics

FUTURE PLANS

New Contract

Contracts awarded....further expansion to included multiple contracts...additional data bases...

Summary

- Addition of EHR data sources
- Access to data 1 – 4 months old
- Use of a flexible and expandable CDM
- Access to flexible analytic capabilities
- Use of innovative methods to identify and report blood transfusion-related adverse events
- Significant cost reduction

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ADMINISTRATION

Thank you